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10/585,503

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Owen P. Hamill

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EXAMINER

HALVORSON, MARK

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/585,503 | Applicant(s) HAMILL ET AL. | |
| | Examiner Mark Halvorson | Art Unit 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/27/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-34 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-10, drawn to a method for identifying an agent that decreases activity of a mechanosensitive Ca^{2+} channel comprising contacting a motile cell expressing said channel with a candidate agent.

Group 2, claim(s) 11, drawn to an agent that decreases activity of a MscCa channel.

Group 3, claim(s) 12-18, drawn to a method for identifying an agent that decreases a phenotype of a cell comprising contacting an MscCa channel with a candidate agent to yield a treated cell.

Group 4, claim(s) 19, drawn to an agent that decreases the phenotype of a cell that expresses an MscCa channel.

Group 5, claim(s) 20-34, drawn to a method for treating cancer comprising administering to a subject having cancer an effective amount of a composition comprising an agent that decreases activity of a mechanosensitive ion channel.

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding, special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the

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category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c), 37 C.F.R. 1.475(d)

The invention listed as Groups 1-5 do not relate to a single inventive concept under PCT Rule 1.31 because, under PCT 13.2 they lack the same or corresponding special technical feature for the following reasons:

The technical feature linking Groups 1-5 appears to be a method for identifying an agent that decreases activity of a mechanosensitive Ca^{2+} permeable (MscCa) channel comprising contacting a cell expressing an MscCa channel with a candidate agent wherein decreased activity of an MscCa channel indicates that the candidate agent decreases the activity of an MscCa channel.

However, Yao et al., (FASEB Journal, May 2000, Vol. 14, pages 932-938) identify a mechanosensitive Ca^{2+} permeable cation channel and teach that inhibition of this channel abolished the rise of calcium ions (page 932, second column, last paragraph). Yao *et al.* further identify agents that decrease the activity of said channels in cells compared to controls (page 936, second column).

Therefore, the technical feature linking the inventions of Groups 1-8 does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

Thus, the different groups in the present application do not contain a single inventive concept and puts a serious search burden on the Examiner.

SPECIES ELECTION

This application contains claims directed to the following patentably distinct species of the claimed invention. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

(i). **Group 1** is subject to election of at least one of the disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct measurements for examining cell activity whereby the measurements are selected from the group consisting of: **(a) decreased motility (b) decreased invasiveness, (c) decreased proliferation and (d) increased apoptosis.** The species are independent or distinct because they are different methods with different readouts.

(ii). **Group 5** is subject to election of at least one of the disclosed species of agents.

Claims 20 is generic to a plurality of disclosed patentably distinct species of agents, the agents being **(a) a polypeptide comprising an amino acid sequence of SEQ ID NO:7, (b) a polypeptide comprising an amino acid sequence of SEQ ID NO:1 (c) an antibody that binds to an epitope on SEQ ID NO:5, (d) an antibody that binds to an epitope on SEQ ID NO:6, an RNA polynucleotide**

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Examination will begin with the elected species. As per MPEP 803.02, if the elected species is found to be unpatentable, the provisional election will be given effect and all other claims to species will be withdrawn from consideration. If the elected

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species is found to be allowable, the search will be expanded by the Examiner to consider additional species and subgenuses within the generic formula until:

- I. An art rejection can be made.
- II. The genus claim is found to lack unity of invention.
- III. The claims have been searched in their entirety.

Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during

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prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson
Patent Examiner
571-272-6539

/MISOOK YU/
Primary Examiner, Art Unit 1642